The terms of the Kelkar Committee has been extended to examine and consider various recommendations received by it.

**Release of anti-Ashthama Drugs**

1066. SHRI CHANDRIKA PRASAD TRIPATHI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to refer to the answer to Unstarred Question No. 1679 given in Rajya Sabha on 11th May, 1988 and state:

(a) whether it is a fact that Ventorlin CR is a sustained release preparation based on Salbutamol;

(b) whether it is a fact that the same has been allowed for marketing in the country in 4 mg and 8 mg tablets;

(c) whether dissolution study, blood level studies and other criteria evaluating invivo effects of the drugs was done;

(d) if so, what are the details of reports;

(e) the preparation has been allowed for human consumption without the permission of Government, the action taken;

(f) if not; and

(g) what were the tests conducted alongwith the report of each?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) to (g) Although control release preparations of old drugs would fall under the definition of 'now' drug as per the "Guidelines on Introduction of New Drugs", the State Drugs Controllers, in the absence of guidelines not under statute yet, may have been from time to time in consultation with their experts granting permission of control release preparations of old drugs including the one under Question.

The Central Government has no information as to whether permission of such control release preparatinos were granted on the basis of blood level studies, since such permissions were granted by the State Drugs Control Authorities.

**Clearnace of combination Diclofenac Sodium and Paracetamol for marketing**

1067. SHRI CHANDRIKA PRASAD TRIPATHI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that combination of Diclomenac Solium with Paracetamol has been allowed for marketing in the country by State Drug Authorities, Gujarat

(b) if so, what is the rational thereof and whether the Ministry of Health and Family Welfare has studied and approved the rationality;

(c) whether any trials was conducted in the country for this combination;

(d) if so, the details thereof;

(e) whether this combination is being marketed in any other country of the would;

(f) the names of those countries;

(g) whether any expert were consulted before granting permission;

(h) if so, the names of the experts alongwith the details of findings of each;

(i) whether Ministry of Health and Family Welfare has studied the reports, date and are satisfied therewith; and

(j) if not, by when the Ministry proposes to study the rationality and other factors involved in the matter?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) to (j) Although fixed dose combination of drugs like Diclofenac Sodium and Paracetamol would fall under the purview of the